## REMARKS/ARGUMENTS

Claims 1-6, 8-20 and 22-23 remain in this application. Claim 21 has been canceled, without prejudice, and claims 1 and 22 have been amended without prejudice to incorporate the limitation of claim 21. Applicants reserve the right to pursue the subject matter of such original claims in subsequent continuation applications. Accordingly, no issues of new matter are believed to be raised by the above amendments to the claims.

**Rejection Under 35 USC 112, First Paragraph**

I

Claim 21 was rejected under 35 USC 112, first paragraph. The Office Action asserts that "claim 21 lacks written description because . . . the claim and specification state no more than a certain percent of water is left after drying at 105° C the time if which the dosage form is dried was not recited." See Page 3 of the Office Action. As discussed above, Applicants have cancelled claim 21, but have incorporated the limitation therein into both claims 1 and 22. With respect to the argument set forth in the Office Action, Applicants respectfully disagree, as the time for the weight of the dosage form to stabilize once heated to 105°C will obviously depend upon the formulation of the dosage form (e.g., the water content of the dosage form at room temperature). Accordingly, Applicants respectfully request that this rejection be withdrawn.

II

Claim 20 was rejected under 35 USC 112, second paragraph. See pages 3-4 of the Office Action. The Office Action asserts that "claim 20 recites tat he dosage form meets USP dissolution requirements for immediate release, but the claim does not describe how the requirement would be met." See page 4 of the Office Action. Applicants respectfully disagree. As set forth on page 3, lines 4-11 of the specification, the USP sets forth a specific requirement for each active. As set forth on page 3, lines 6-11 of the specification;

> For example, for acetaminophen tablets, USP 24 specifies that in pH 5.8 phosphate buffer, using USP apparatus 2 (paddles) at 50 rpm, at least 80% of the acetaminophen contained in the dosage form is released therefrom within 30 minutes after dosing, and for ibuprofen tablets, USP 24 specifies that in pH 7.2 phosphate buffer, using USP apparatus 2 (paddles) at 50 rpm, at least 80% of the ibuprofen contained in the dosage form is released therefrom within 60 minutes after dosing. See USP 24, 2000 Version, 19 – 20 and 856 (1999).

Thus, Applicants believe that the claim 20 is clear, as the specific requirements are set forth in the USP. Accordingly, Applicants respectfully request that this rejection be withdrawn.

**Rejections Under 35 USC 103**

Claims 1-5, 7-12, and 15-23 remained rejected under 35 USC 103(a) as being unpatentable over Buehler et al. (US6432442) in view of McTeigue et al. (US 2002/0031552) in view of Dressman et al. (US5789393). See Page 4-7 of the Office Action. According to the Office Action,

> "Buehler discloses a chewable pharmaceutical dosage form comprised by weight 1-20% gelatin, 10% hydrocolloid including HPC, up to 60% sweetener such as sorbitol and xylitol, [and] the matrix further contains 2-30% of a taste masked coated pharmaceutically active agent including ibuprofen. . . . Buehler does not disclose the exact taste masked coating as claimed by applicants and Buehler is silent on the MW and viscosity in 2% aqueous solution on the HPC matrix. McTeigue is used primarily for the disclosure within the taste masked pharmaceutical particles and chewable tablets made from those particles were well known in the art at the time of the invention . . . Dressman is used only to show that HPC within the MW and viscosity claimed by applicant was well known at the time of the invention. . . . Thus the claimed invention would have been prima facie obvious because the substitution of one known element such as a coating material disclosed within McTeigue for another known element such as the coating materials disclosed within Buehler would have yielded predictable results to one of ordinary skill in the art at the time of the invention."

See pages 5-6 of the Office Action. Applicants respectfully disagree.

Applicants have amended the pending claims to now recite an immediate release compressed tablet dosage form "wherein said dosage form has a moisture content of not more than about 5 percent as measured by weight loss on drying at 105 degrees Celsius." Buehler et al. fails to disclose, or suggest, such a dosage form. Rather, Buehler at al. discloses a chewable gelatin matrix dosage form, not a tablet. As discussed on pages 1-2 of the specification:

> [Buehler et al.] discloses the use of a gelatin matrix and an optional hydrocolloid as another technique for providing a soft, chewable delivery system. Because these "gummi" or confectionary systems also contain water in an amount of from about 10 to 30 percent by weight of the final product, they disadvantageously possess certain limitations with respect to shelf-life, packaging, and storage conditions. Additionally, it is economically more beneficial to produce other dosage forms such as, for example, compressed tablets, due to their simplicity of processing (emphasis added).

Specifically, Buehler et al discloses on col. 5, lines 18-22. "Water is used to hydrate both the gelatin and hydrocolloid, and makes up the remainder of the dry product weight. Water is present in the final product at levels of from about 10 to 30 weight percent, more typically, water is present at a level at about 20 to about 25 weight percent. Thus, Buehler et

al. does not teach a compressed tablet, nor does it teach a product comprising the claimed moisture content.

Further, the Office Action on page 6 asserts, "since the use of HPC within applicants claimed MW range was already well known to be useful in pharmaceutical compositions as shown by Dressman applicants claimed HPC was a known option available at the time of the invention and someone of ordinary skill in the art would have high expectation of success in using the specific MW of HPC disclosed within Dressman and substitute those for the HPC disclosed with McTeigue." Applicants again respectfully disagree.

While Dressman may disclose the use of such specific molecular weight of HPC as in the present invention, the reference does not disclose, or suggest, the use of such ingredient in a chewable tablet. Thus Applicants do not agree with the assertion that someone of ordinary skill in the art would have a "high expectation of success" in using the ingredient in a chewable tablet.

Further, Applicants unexpectedly found benefits is using such an ingredient in the chewable tablets of the present invention. As set forth on page 11, lines 3-13 of the specification:

> We have unexpectedly found that the addition of high weight average molecular weight hydroxyalkylcellulose to the matrix results in a dosage form that delivers a good mouthfeel through a rapid viscosity build without an initial intense drying sensation of the mouth and without a subsequent excessive slimy or gummy feel during mastication. Although the increase in viscosity will depend upon several factors such as, for example, the amount and molecular weight of such hydroxyalkylcellulose used and the amount and type of active ingredient, generally the use of about 0.1 percent to about 25.0 percent of a 60,000 to about 5,000,000 MW hydroxyalkylcellulose based upon the total weight of the dosage form, will result in a viscosity increase during tablet mastication that is similar to that obtained using gums, but without the drying sensation and without the subsequent excessive slimy or gummy feel imparted by using conventional agents.

Accordingly, Applicants assert that the presently claimed invention would not have been obvious to a person of ordinary skill in the art at the time of the claims invention was made in light of these references. Thus, Applicants respectfully request that this rejection under 35 USC 103(a) be withdrawn.

**Conclusion**

For the foregoing reasons, the present application is in condition for allowance. Accordingly, favorable reconsideration of the amended claims in light of the above remarks and an early Notice of Allowance are courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner

is requested to telephone the undersigned Attorney at the below-listed number.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/MCP-5014/WEM.

Respectfully submitted,

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